Sponsor Information & Training Day

Tuesday 9 September 2014
Hyatt Hotel, Canberra

Session B3
Advertising for Medical Devices

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Presentation Outline

- Advertising Overview
- Advertising to Consumers
  - Legislative requirements and Therapeutic Goods Advertising Code
- Advertising to Healthcare Professionals
  - Industry Codes of Practice
- Advertising FAQs & Practical Examples

Advertising Overview

Advertising framework in Australia for medical devices

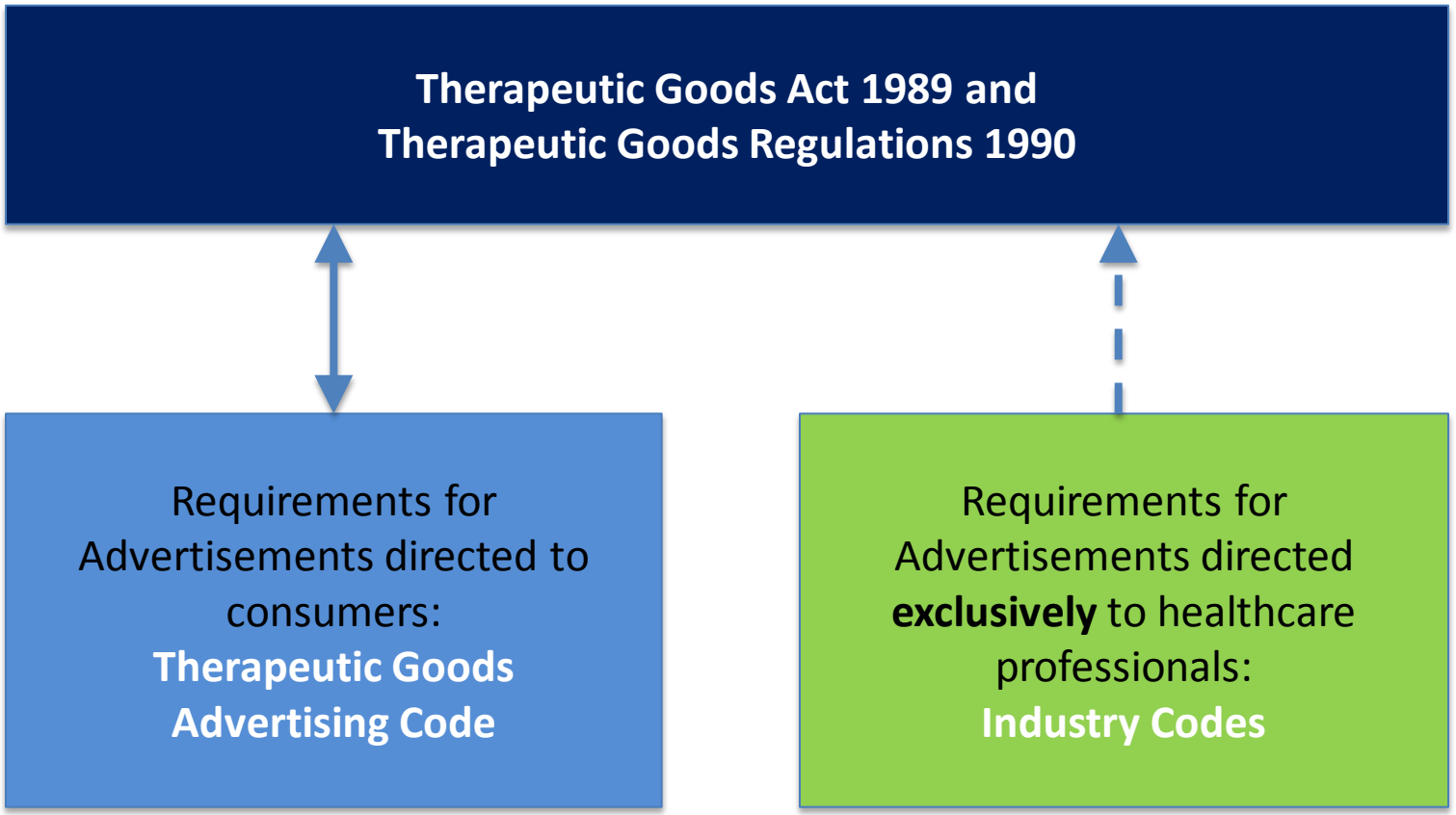
Three Levels of Controls

- REGULATION - legislation administered by the TGA
  - Therapeutic Goods Act 1989
  - Therapeutic Goods Regulations 1990
  - Therapeutic Goods Advertising Code (TGAC)

- CO-REGULATION – functions shared with Industry
  - Advertising directed to consumers
  - Therapeutic Goods Advertising Code Council (TGACC)
  - Complaints Resolution Panel (CRP)

- SELF-REGULATION – not in legislation
  - Advertising directed to healthcare professionals
  - Voluntary industry codes of conduct/practice
  - Industry association complaints and monitoring panels

Advertising Framework



Advertising Requirements

- The advertising requirements are set out in the
  - Therapeutic Goods Act
  - Therapeutic Goods Regulations
  - Therapeutic Goods Advertising Code
  - Price Information Code of Practice
- Advertising requirements are also set out in the Competition and Consumer Act

Goal = truth in advertising

- A robust and effective system of advertising controls
  - Ensures responsible advertising
  - Reinforces the quality use of therapeutic goods
  - Provides for consumer confidence and trust
  - Enhances the health outcomes of all Australians

Australian Government
Department of Health
Therapeutic Goods Administration

Advertising Therapeutic Goods to Consumers

Complying with the legislation

Mick O'Connor
Director
Recalls & Advertising Section
Office of Product Review

TGA Health Safety Regulation

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The Role of the TGA

- Administers the legislation which underpins the advertising framework
- Oversees the shared regulatory arrangements with industry associations
- Initiates further regulatory action to obtain advertising compliance where required
- Chair and member of TGACC
- Observer on complaints panels

Therapeutic Goods Act 1989

Chapter 1- Preliminary

- Advertisement is defined in Section 3 - Interpretation:

  "...any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to ***promote the use or supply of the goods****"*

Therapeutic Goods Act 1989

Chapter 4 – Medical Devices

- Subsection 41ML: Offence for Medical Devices
  - Advertising an intended purpose not accepted in relation to the inclusion of the device in ARTG
  - Applies to ads for HCPs and consumers

- s41FN(5) - The inclusion of a kind of medical device in the Register is subject to a condition that advertising material relating to medical devices of that kind is consistent with the intended purpose as certified under section 41FD.

Therapeutic Goods Act 1989

Chapter 5; Part 5-1 – Advertising

- Provides for:
  - exemption for advertisements directed exclusively to health professionals
  - advertising definitions
  - establishes the Advertising Code
  - prohibited and restricted representations
  - offences

Therapeutic Goods Regulations 1990

- Part 2
  - establishes approval scheme for certain “specified media” advertisements
  - provides for the TGA to issue orders
- Part 6, Divisions 2 & 3
  - establishes TGACC & CRP and their procedures
  - provides for the complaints register

Therapeutic Goods Advertising Code

Object

- To ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer

Application

- The conformity of an advertisement with the Code is assessed in terms of its probable impact upon the reasonable person to whom the advertisement is directed

Therapeutic Goods Advertising Code

General Principles

- Section 4 sets out the key requirements including that therapeutic good advertisements **"must not"**:
  - Mislead or be likely to mislead
  - Arouse unrealistic expectations of product effectiveness
  - Lead consumers to self-diagnosing, inappropriately treating or believing they have a serious disease
  - Abuse consumers' trust or exploit their lack of knowledge
  - Encourage inappropriate or excessive use
  - Claim that a good is guaranteed, certain, sure cure or that the goods are completely safe or harmless
  - Be directed to minors (subject to exceptions).

Prohibited Representations

Section 5(1) and Appendix 6, Part 1 of the Code

- An advertisement must not contain, expressly or by implication, certain representations. Includes representations regarding abortifacient action or the treatment, cure or prevention of the following diseases:
  - Neoplastic disease
  - Sexually Transmitted Diseases (STD)
  - HIV AIDS and/or HCV
  - Mental illness
- Note there are some exceptions which become restricted representations.

Restricted Representation

Section 5(2) and Appendix 6, Part 2 of the Code

- A ***Restricted representation*** in an advertisement for therapeutic goods is a reference (whether expressly or by implication) to a serious form of disease, condition, ailment or defect specified in Table 1 of the Code
- An advertisement that refers to a restricted representation requires approval for the reference before the advertisement is published or broadcast

Advertising Complaints

- Complaints about medical device advertisements directed to the public that do not comply with the advertising requirements can be made to the:
  - ✓Complaints Resolution Panel – TV, radio, newspapers, magazines, cinemas, posters
  - ✓Medical Technology Association of Australia – in-store material, brochures
  - ✓Therapeutic Goods Administration

Advertising Compliance

- Complaints considered by the Complaints Resolution Panel may result in the advertiser being requested to take certain actions
- The Panel may make a recommendation to the Secretary of the Department of Health (TGA)
  - Where the Advertiser fails to respond, or fails to indicate an intention to comply fully with Panel's requests.

Recommendations to Secretary

- The Panel may recommend that Secretary orders the Advertiser to
  - withdraw an advertisement
  - withdraw claim or representation
  - publish a retraction or correction
- May also recommend that the Secretary take other regulatory actions

The Secretary's Order

- Secretary's delegate in TGA reviews afresh the complaint and the Panel's findings
- Based on this review the delegate may decide to order the Advertiser under regulation 9 to
  - withdraw an advertisement
  - withdraw claim or representation
  - publish a retraction or correction
- Consequences of non-compliance with order and rights for 'review' advised

Advertising Tips

1. Hold the appropriate level of evidence
2. Claims must be consistent with intended purpose
3. No references to prohibited or unapproved restricted representations, "*TGA approved*" or to the product being safe
4. Endorsements and testimonials must comply fully with the Code
5. Include mandatory warning statements

Australian Government

Department of Health

Therapeutic Goods Administration

Advertising to Healthcare Professionals

Complying with a Code of Practice

Gary Burgess (MTAA)

Industry Code of Practice

- MTAA has developed the Medical Technology Industry (MTI) Code of Practice to facilitate ethical interactions with healthcare professionals and others.
- The MTI Code is a self-regulatory industry code that addresses key areas of industry activity, including advertising material.
- The MTI Code is required to be followed by MTAA members.
- Non-members are encouraged to follow it on a voluntary basis.
- The MTI Code is currently undergoing a scheduled review.

Healthcare Professionals (HCP)

- **Section 6** of MTI Code applies to an Advertisement that is directed ***exclusively*** to Healthcare Professionals, including:
  - Medical practitioners
  - Dentists
  - Pharmacists
  - Scientists working in medical laboratories
  - Nurses
  - Purchasing officers in hospitals
  - Persons engaged in business of wholesaling therapeutic goods

General Requirements

Section 6.1

- Must not be misleading or deceptive
- Reflect a high standard of social responsibility and conform to generally accepted standards of good taste
- Recognised by target audience as an Advertisement
- Must not claim a device is unique or has special properties unless claims can be substantiated

General Requirements

Section 6.1

- Do not use term “safe” without appropriate qualification
- Don’t claim device is “new” more than 1 year after product launch
- Don’t imitate the branding, names, logos, graphic design, copy, slogans, or general layout adopted by a competitor in a way that is likely to mislead, deceive or confuse

Claims and endorsements

Section 6.2(a)

- Must be able to substantiate all claims by reliable technical, scientific or other support
- Cite source of claim where the claim is likely to mislead or deceive if its source is not cited
- If a third party requests substantiation of a claim - provide info within 10 work days
- Identify any unpublished data as “data on file” when citing in a claim

Comparative advertising

Section 6.3

- An Advertisement may not denigrate a competitor's product

- Can report on outcome of comparative testing, provided:
  - Technologies have been subjected to the same and appropriate testing;
  - Outcomes are reported in fair and balanced way; and
  - Each outcome is referenced and consistent with body of evidence.

Comparative advertising

Section 6.3

- If the comparative data arises from separate studies, a qualifying statement must be included that the data arise from separate studies

- Don’t show a competitor product as broken or defaced, inoperative or ineffective

Mandatory information

Section 6.4

- Brand name of medical device
- Name and contact details of the Sponsor
- Claims consistent with the intended purpose
- All other information required by law or as a condition of a licence

Social media

Section 6.6

- Social media includes Facebook, LinkedIn, Instagram, wikis, blogs etc.

- All use of social media by Companies in the promotion of products to HCPs must comply with the Code, the same as any other form of advertisement

Frequently Asked Questions

Devices not included in ARTG

- **Q:** *Are you able to promote the supply of a device that is yet to be included in the ARTG?*

- **A: No.**
  - **HCPs:** 41MM of the Act says a person is guilty of an offence if they claim to be able to arrange the supply of a device that isn't included in the ARTG and it isn't exempt.

  - **Consumers:** 41MM also applies, and 42DL(g) of the Act says a person must not publish an advertisement about goods not entered in the ARTG.

Claiming TGA approval

- **Q:** *Is an advertisement allowed to say that a device is TGA or FDA "approved"?*

- **A: No. But stating the ARTG # is OK.**
  - **HCPs:** implying an endorsement by a regulator is against the Competition & Consumer Act.
  - **Consumers:** 42DL(e) of the Act and 6(b)(i) of the Advertising Code say a person must not publish an ad that implies an endorsement by a government agency.

Pre-approval of advertisements

- **Q:** *Do advertisements for medical devices require pre-approval by the TGA?*

- **A: No, except for ads to consumers with restricted representations.**
  - **HCPs:** No pre-approval required.
  - **Consumers:** Only require pre-approval under 42DF if they contain Restricted representations (Part 2 of Appendix 6 of the Advertising Code).

Claims of intended purpose

- **Q:** *Can you advertise a device for a purpose that is outside the intended purpose stated in the ARTG entry?*

- **A: No.**
  - **HCPs and Consumers:**
    - ARTG condition under 41FN(5) requires advertising to be consistent with intended purpose.
    - Under 41ML it is an offence to falsely advertise a device for a purpose that has not been accepted.

Testimonials & endorsements

- **Q:** *Can an advertisement contain a testimonial or endorsement from a HCP or patient?*

- **A: Sometimes, under certain circumstances.**
  - **HCPs:** allowed, but must comply with industry Code.
  - **Consumers:** 4(6)(b) of the Advertising Code does not allow recommendation by HCPs, clause 4(7) does allow testimonials but they must be documented, genuine, not misleading and illustrate typical cases only.

For HCPs only

- **Q:** *When advertising a device to HCPs on my website, is it OK to just include a disclaimer indicating it is not intended for consumers?*

- **A: No.**
  - You need to ensure consumers are not able to view advertisements that are intended ***exclusively*** for HCPs.
  - This can be achieved by requiring HCPs to log in to a secure part of the website to view the advertising material.
  - If a patient can view the advertisement, then this will be treated as advertising to consumers, and must meet the relevant requirements.

Hypothetical Example

Recognising possible breaches of advertising requirements

Hypothetical Newspaper Ad

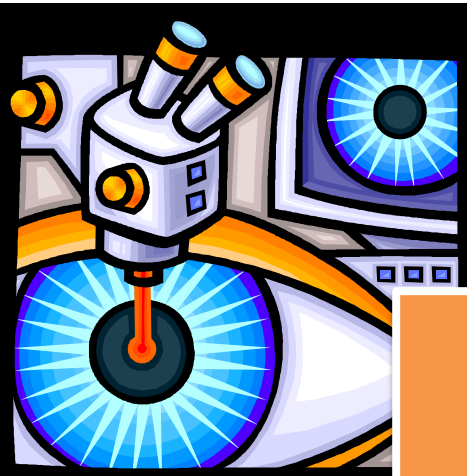
Dr. Evil™ Eye "LASER"

The innovative and stylish design of the Dr. Evil™ Eye "LASER" enhances the patient appeal of any practice. It is available exclusively through Dr Evil Industries (Australia) Pty Ltd.

- The latest treatment for blindness!
- TGA, FDA and CE approved!
- ARTG # 12345
- Fully compliant with the requirements of the Therapeutic Goods Act 1989!

- Safe, effective & fast!
- Proven clinical results!
- Works every time!
- Designed by leading scientists and medical practitioners
- Endorsed by Dr. Evil himself!

Hypothetical Newspaper Ad



Dr. Evil™ Eye "LASER"

The … sh design of the Dr. Evil …

- Th…
- TG…
- AR…
- Fu… requir…ents of the Therape… Goods Act 1989!

- … scientists and … practitioners
- Endorsed by Dr. Evil himself!

Restricted representation. **Breach: s42DL(1)(c)** if not approved under s42DF

Appr… Gove… aut… **Breach: s42D…(ii)**

Bre… Adve… **Cla…**

Breach: s42DM Advertising Code: **Clause 4(2)(a)**

…e:

Reference to the Act. **Breach: s42DL(e)(i)**

Others? Advertising Code: **Clause 4(2)(j)? Clause 6?**

Breach: s42DM …dvertising Code: **Clause 4(6)(b)**

Questions & Discussion

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